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510(k) Summary

1. Submitter Name, Address, and Date of Submission:

Rick Lykins
Group RA Manager - US
Teleflex Medical Group
Tall Pines Park
Jaffrey, NH 03452
Telephone Number: (603) 532-0204
Fax Number: (603) 532-6179

Contact: Same as above

2. Name of the Device, Common, Proprietary (if known), and Classification:

Classification Name:	Smooth or Threaded Metallic Bone Fixation Fasteners
Common Name:	External Fixation Devices
Proprietary Name:	KMedic External Fixation Devices

3. Identification of the legally marketed device to which the submitter claims equivalence:

The KMedic External Fixation Devices are substantially equivalent in design and materials to:

- George Tiemann & Co. Kirschner Wires, Steinmann Pins and Cerclage Wires - Preamendment
- DuPuy, Inc. Kirschner Wires and Steinmann Pins - Preamendment (As referenced in DuPuy, Inc. Sterile Kirschner Wires and Steinmann Pins K960385)
- NewDeal K-Wire - K022599

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4. Description of the Device:

The KMedic External Fixation Devices consist of various fixation pins and wires for use in unilateral external fixation. The various lengths, sizes and end configurations are offered to accommodate various patient anatomies, injuries and/or conditions, and physician preference. All KMedic external fixation devices included in this submission are manufactured of medical grade stainless steel. All KMedic external fixation devices included in this submission will be offered in a non-sterile condition.

The following KMedic External Fixation Devices are included in this submission:

Kirschner Wires
Steinmann Pins
Schanz Pins
Cerclage Wires

5. Intended Use of the Device:

The KMedic External Fixation Devices are non-sterile, single-use, external fixation devices intended to be used for unilateral external fixation in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality.

6. Summary of Technological Characteristics:

The technological characteristics are the same as or equivalent to the predicate devices previously listed.

Materials:

The KMedic External Fixation Devices are manufactured from 316 stainless steel which is identical to all of the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 6 2003

Mr. Rick Lykins
Group RA Manager - US
Teleflex Medical Group
50 Plantation Drive
Jaffrey, New Hampshire 03452

Re: K030336
Trade Name: KMedic External Fixation Devices
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JDW and HTY
Dated: January 29, 2003
Received: January 31, 2003

Dear Mr. Lykins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Milhous

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030336

Device Name: KMedic External Fixation Devices

Indications for Use:

The KMedic External Fixation Devices are non-sterile, single-use, external fixation devices intended to be used for unilateral external fixation in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ **OR** **Over-The-Counter Use** ____
(Per 21 CFR 801.109)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030336

(Optional Format 1-2-96)